**UPN0026-500 (Q3474)**

What is claimed is:

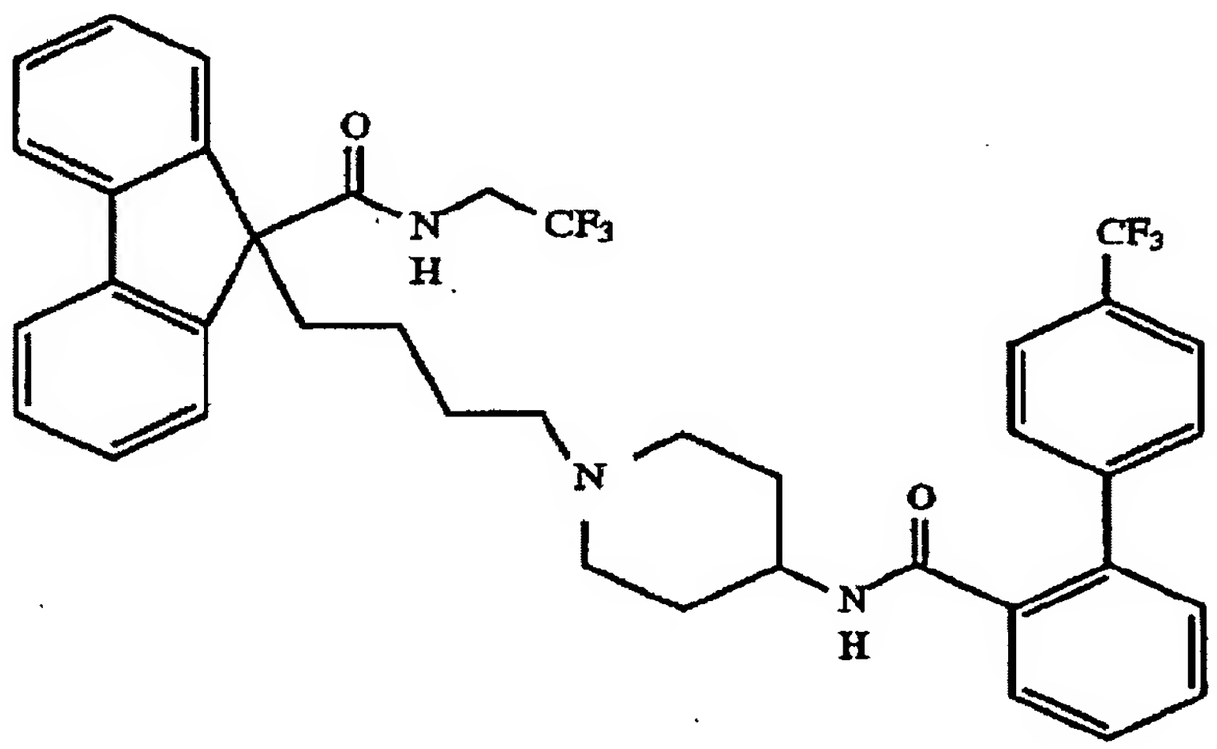
1. A method of treating a subject suffering from a disorder associated with hyperlipidemia and/or hypercholesterolemia, the method comprising administering to the subject an amount of an MTP inhibitor effective to ameliorate the disorder, wherein said administration comprises at least three step-wise, increasing dosages of the MTP inhibitor.

2. The method of claim 1 wherein the disorder is severe hypercholesterolemia.

3. The method of claim 1 wherein one or more of Total Cholesterol, LDL, fasting triglycerides (TG), VLDL, lipoprotein (a) (Lp(a)), and apolipoproteins A-I, A-II, B, and E are reduced by at least 15%, compared to control levels.

4. The method of claim 1 wherein one or more of Total Cholesterol, LDL, fasting triglycerides (TG), VLDL, lipoprotein (a) (Lp(a)), and apolipoproteins A-I, A-II, B, and E are reduced by at least 25%, compared to control levels.

5. The method of claim 1 wherein said MTP inhibitor has the structure:




or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof.

6. The method of claim 1 wherein the MTP inhibitor is administered orally.

**UPN0026-500 (Q3474)**

7. The method of claim 1 wherein said escalating doses comprise at least a first dose level, a second dose level, and a third dose level.

8. The method of claim 7 wherein said escalating doses further comprise a fourth dose level.

9. The method of claim 7 wherein said escalating doses further comprise a fourth and a fifth dose level.

10. The method of claim 9 wherein the first dose level is 6.25 mg/day, the second dose level is 12.5mg/day, the third dose level is 25mg/day, the fourth dose level is 37.5 mg/day, and the fifth dose level is 50mg/day.

11. The method of claim 1 wherein each of said escalating dose levels is no more than 50% of the immediately following dose level.

12. The method of claim 1 wherein each of said escalating dose levels is no more than 20% of the immediately following dose level.

13. The method of claim 9 wherein said first dose level is from about 2 to about 13 mg/day, said second dose level is from about 5 to about 30mg/day, and said third dose level is from about 10 to about 50 mg/day, said fourth dose level is from about 20 to about 60 mg/day, and said fifth dose level is from about 30 to about 75mg/day.

14. The method of claim 8 wherein the first dose level is 12.5 mg/day, the second dose level is 25mg/day, the third dose level is 37.5mg/day, and the fourth dose level is 50mg/day.

15. The method of claim 7 wherein the first dose level is 6.25 mg/day, the second dose level is 12.5mg/day, and the third dose level is 50mg/day.

**UPN0026-500 (Q3474)**

16. The method of claim 1 wherein said MTP inhibitor is administered to said subject in combination with a further lipid modifying compound.

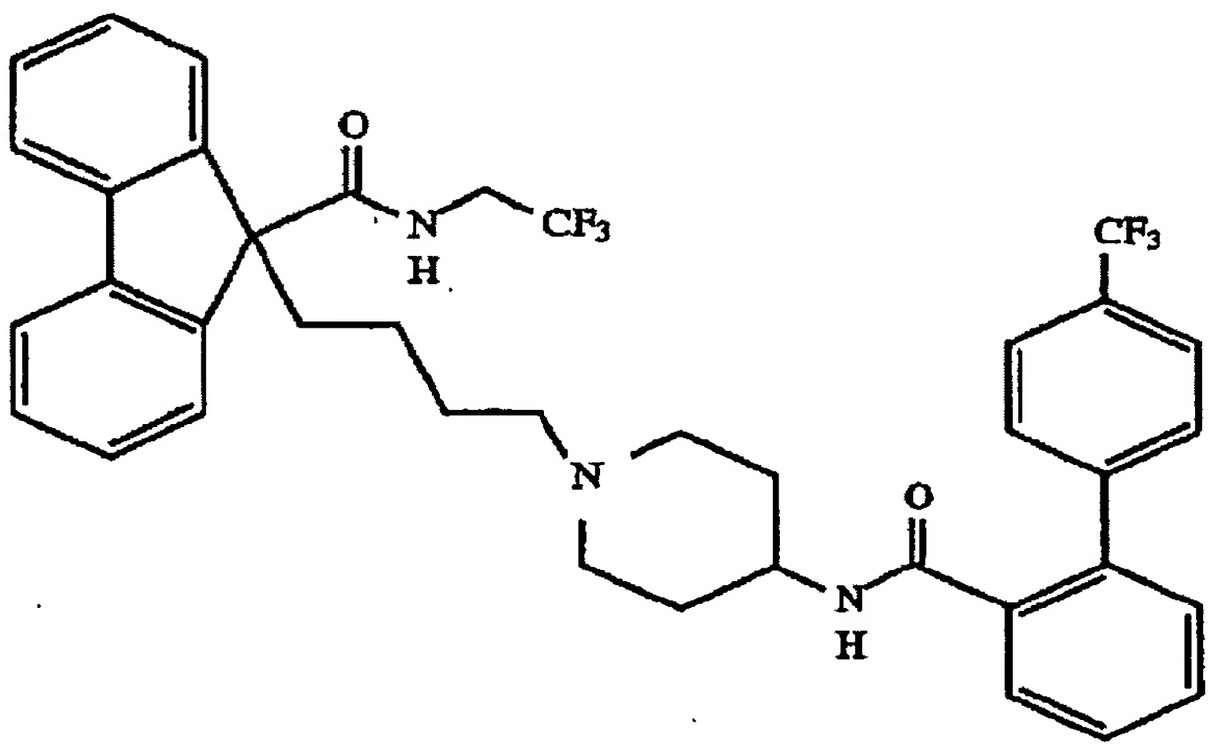
17. The method of claim 1 wherein each dose level is administered to the subject for from about 1 to 4 weeks.

18. The method of claim 16 wherein the MTP inhibitor and the lipid modifying compounds are present in the same dosage unit.

19. A method for inhibiting MTP in a subject in need thereof comprising administering to the subject an amount of an MTP inhibitor effective to inhibit MTP, wherein said administration comprises at least three step-wise, increasing dosages of the MTP inhibitor.

20. The method of claim 17 wherein said MTP inhibitor is administered to said subject in combination with a further lipid modifying compound.

21. The method of claim 17 wherein the MTP inhibitor has the structure:




or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof.

**UPN0026-500 (Q3474)**

22. The method of claim 19 wherein one or more of Total Cholesterol, LDL, fasting triglycerides (TG), VLDL, lipoprotein (a) (Lp(a)), and apolipoproteins A-I, A-II, B, and E are reduced by at least 15%, compared to control levels.

23. The method of claim 20 wherein the lipid modifying compounds are selected from the group consisting of HMG CoA reductase inhibitors, cholesterol absorption inhibitors, ezetimide, squalene synthetase inhibitors, fibrates, bile acid sequestrants, statins, probucol and derivatives, niacin, niacin derivatives, PPAR alpha agonists, fibrates, PPAR gamma agonists, thiazolidinediones, and cholesterol ester transfer protein (CETP) inhibitors.

24. A kit for treating a disorder associated with hyperlipidemia and/or hypercholesterolemia in a subject, comprising:

a) at least four sets of pharmaceutical dosage units, wherein a first set of dosage units provides 6.25mg/day for a first interval, a second set of dosage units provides 12.5 mg/day for a second interval, a third set of dosage units provides 37.5mg/day for a third interval, a fourth set of dosage units provides 50mg/day for a third interval; and

b) instructions for use.

25. The kit of claim 24 further comprising a fourth set of dosage units, said fourth set providing 75mg/day for a fourth interval.